K093019

DEC 22 2009

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Enamelite, LLC
1753 B Alpine Drive
Clarksville, TN 37040

2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: Enamelite Acryseal Spray Sealant
CFR Section 872.3760
Denture relining, repairing, or rebasing resin
Class II
Product Code: EBI

4. Common/Trade Name:

Enamelite Acryseal
Enamelite Acryseal-CB

Description:

Enamelite Acryseal Spray Sealant is a dental sealant or bonding agent which is packaged for aerosol dispensing. The product is formulated as either an acrylic spray sealer or composite spray sealer. The base product is identical to brush on sealants that have been used for over 40 years in the dental profession. The spray on sealant and bonding agent produces the same finished material surface as commonly used brush-on sealants. Enamelite Acryseal Spray sealing and bonding agent produces a much smoother coating compared to a brush-on method and was designed to replace the outdated brush application of sealing/bonding lacquer.

Indications for Use:

Enamelite Acryseal and Enamelite Acryseal-CB Spray Sealant is intended for use as a sealant/bonding agent intended to reline, repair, or rebase denture surfaces and CAD/CAM produced/milled acrylic and composite replacement dental restorations.

Technological Characteristics:

Enamelite Acryseal Spray Sealant is provided in an aerosol can in two formulations. The Acryseal product is provided as an acrylic spray, which is principally composed of Methyl Methacrylate Solids and Monomers; and the Acryseal-CB product is a composite spray, which is principally composed of 2-Methyl-2-Propenoic Acid (1 Methylethylidene) Bis {4,1-Phenyleneoxy (2-Hydroxy-3, 1-propanediyl)} Ester and Triethylene Glycol Dimethacrylate. Barium Oxide filler and Amorphous Silica may be incorporated in the formulation.

The products are supplied in aerosol cans with DYMEL™ Dupont (1,1-difluoroethane) propellant. Available sizes are
0.5 oz., 1 oz., 2 oz., and 4 oz. Products supplied in aerosol form do not dry out and change consistency which can happen after opening of brush-on products.

Product is sprayed onto dental fixtures in very light or thin coats. The dental acrylic sealant begins its chemical bonding process as soon as the material hits the surface of the dental fixture. The acrylic sealant can be air cured in 5 minutes and the composite sealant can be light cured in 90 seconds. Spray sealant facilitates a smooth even layer of material when sprayed onto dental fixtures. Surface porosity and any scratches are sealed and smoothed over to a glossy smooth surface to make cleaning easier and help prevent the growth of harmful bacteria.

Substantial Equivalence:

Enamelite Acryseal Acrylic Spray and Enamelite Acryseal-CB Spray are substantially equivalent to Lang Dental Acrylic Primer (K081981), Palaseal (K892452), and Apex Dental Surpass (K061981) .

Each of the devices have similar technical features, indications for use, and the safety and effectiveness of the devices is equivalent.

Conclusions:

The predicate devices and the Enamelite Acrylic Spray products share similar indications and identical materials of construction. The Enamelite product is equivalent to the predicate device products in all key areas of features and performance that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Enamelite L.L.C.
C/O Mr. David C. Furr
FDC Services, L.L.C.
8708 Capehart Cove
Austin, Texas 78733

Re: K093019
Trade/Device Names: Enamelite Acryseal Spray Sealant and
Enamelite Acryseal-CB Spray Sealant
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Codes: EBD and EBI
Dated: December 14, 2009
Received: December 16, 2009

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K093019**

Device Name: Enamelite Acryseal Spray Sealant
Enamelite Acryseal-CB Spray Sealant

Indications for Use:

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Prescription Use__X__ or Over-the-counter use
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Beer DDS for Dr. K.P. Mulry (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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